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OPINION: Off Label Prescribing
APPROVED DATE: 03/28/2014
REVISED DATE:
ORIGINATING COMMITTEE:
ADVANCED PRACTICE COMMITTEE

ADVISORY OPINION OFF LABEL PRESCRIBING DRUGS, DEVICES, AND THERAPEUTICS

RATIONALE

These guidelines are intended to assist the RNP in responsible prescribing of off label medications and treatments. RNPs who prescribe off label medications or treatments should use sound clinical judgment, utilizing the following guidelines of responsible professional practice.

STATEMENT OF SCOPE

It is within the Scope of Practice for a registered nurse practitioner (RNP) with prescribing privileges, to prescribe or recommend a prescription drug off-label, device and/or therapeutics based upon the RNP incorporation of knowledge derived from the RNP's advanced education, evidence-based research, and/or established practice standards within a RNP's area of expertise.

For the purposes of this AO, **therapeutics is defined** as the treatment and care of a patient for the purpose of both preventing and combating disease or alleviating pain or injury.

For the purposes of this AO, **off label, prescribing is identified** as the use of FDA approved medications for other than their intended indications and does not include those drugs or uses classified as experimental.

REFERENCES

1. Arizona State Board of Nursing (2013, September). Nurse Practice Act.
2. National Center for Biotechnology Information, U.S. National Library of Medicine. (2013). Off-label drug information. Regulation, distribution, evaluation, and related controversies. Retrieved from <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2799128/>
3. Stafford, R. (2008). Regulating off-label drug use – rethinking the role of the FDA. *New England Journal of Medicine* (358), 1427-1429 DOI: 10.1056/NEJMp0802107
4. United States Department of Health and Human Services. (2013). Off-label” and investigational use of marketed drugs, biologics, and medical devices – informational sheet. Retrieved from <http://www.fda.gov/regulatoryinformation/guidances/ucm126486.htm>